

**European Union comments for the**  
**CODEX COMMITTEE ON CONTAMINANTS IN FOOD**  
**14<sup>th</sup> Session**

**CL 2020/23/OCS-CF:**

**Request for comments on the proposed draft maximum levels for total**  
**aflatoxins in certain cereals and cereal-based products including foods for**  
**infants and young children**  
**(CX/CF 20/14/10)**

*European Union Competence*  
*European Union Vote*

The European Union (EU) welcomes and appreciates the work done on the setting of maximum levels (MLs) for aflatoxins total by the electronic Working Group chaired by Brazil and co-chaired by India.

**BACKGROUND**

Aflatoxins are genotoxic and carcinogenic substances. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) updated the aflatoxin risk assessment at its 83<sup>rd</sup> meeting in November 2016<sup>1</sup>.

JECFA reaffirmed the conclusions of previous assessment that aflatoxins are among the most potent mutagenic and carcinogenic substances known and that the reduction of dietary total aflatoxin exposure is an important public health goal. Five food commodities (maize, peanuts, rice, sorghum and wheat) were identified to contribute each more than 10% to international dietary exposure estimates for more than one GEMS/Food cluster diet, for either AFT or AFB1. The Committee recommends that efforts continue to reduce aflatoxin exposure using valid intervention strategies, including the development of effective, sustainable and universally applicable pre-harvest prevention strategies. Maize and groundnuts are a traditional focus for aflatoxin management. Based on their contribution to dietary aflatoxin exposure in some areas of the world, JECFA recommended that rice, wheat and sorghum would need to be considered in future risk management activities for aflatoxins.

The European Food Safety Authority (EFSA) has recently performed a risk assessment of aflatoxins in food<sup>2</sup>. The CONTAM Panel noted that the calculated Margins of Exposure MOEs are less than 10,000, which raises a health concern. The estimated cancer risks in

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<sup>1</sup> Eighty-third meeting of the Joint FAO/WHO Expert Committee on Food Additives Rome, 8–17 November 2016. WHO Food Additives Series: 74 – Safety evaluation of certain contaminants in food. <http://apps.who.int/iris/bitstream/handle/10665/276868/9789241660747-eng.pdf?ua=1>

<sup>2</sup> EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Schrenk D, Bignami M, Bodin L, Chipman JK, del Mazo J, Grasl-Kraupp B, Hogstrand C, Hoogenboom LR, Leblanc J-C, Nebbia CS, Nielsen E, Ntzani E, Petersen A, Sand S, Schwerdtle T, Vleminckx C, Marko D, Oswald IP, Piersma A, Routledge M, Schlatter J, Baert K, Gergelova P and Wallace H, 2020. Scientific opinion – Risk assessment of aflatoxins in food. EFSA Journal 2020;18(3):6040, 112 pp. <https://doi.org/10.2903/j.efsa.2020.6040>

humans following exposure to AFB1 are in-line with the conclusion drawn from the animal data. This conclusion also applies to AFM1 and AFT + AFM1.

## **PROPOSED MAXIMUM LEVELS**

In order to ensure a high level of human protection, the EU is of the opinion that it is of major importance that maximum levels for aflatoxin total are established as low as reasonably achievable (ALARA) by applying good practices to prevent contamination.

**The maximum levels as proposed in Appendix I of CX/CF 20/14/10, proposal 1 as well proposal 2, are in the view of the EU not established according to the ALARA principle and therefore to a large extent not acceptable for the EU.** More details are hereby provided.

### Maximum level proposed for maize grain, destined for further processing

- The data for the years 2011, 2012 and 2013 show an unusual high contamination level compared to the data for the other years in the period 2007-2019 (table 2). The EU is of the opinion that it is appropriate to investigate the reasons for these unusual high levels in these years to verify if these high levels could be related to e.g. specific climatic conditions in these years. In case no or no acceptable explanation can be provided for these unusual high levels in these years, the EU is of the opinion that it should be considered not to take into account the occurrence data of these years for the setting of the maximum levels.
- Occurrence data on contaminants in food are provided to GEMS/Food database by EFSA on behalf of all EU Member States. The origin of the few data reported in Table 1 for individual EU Member States (Belgium, Bulgaria, Cyprus, Finland, France, Germany, Hungary Ireland, Italy, Poland, Romania, Slovakia, Slovenia, Spain) is therefore unclear. The EU proposes not to use these data for the discussion on the establishment of maximum levels.
- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination<sup>3</sup>, should be excluded from further consideration.
- The EU furthermore proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of maize grain (table 4) on the basis of the occurrence data, after the possible exclusion of the data for the years 2011, 2012 and 2013 and after the exclusion of the outliers and the few data in the table as reported to be originating from individual EU Member States.
- The EU consequently proposes to re-discuss the maximum level proposed for maize grain, destined for further processing on this basis taking into account an acceptable rejection rate (<5 %) and the reduction of human exposure to aflatoxins.

### Maximum level proposed for flour, meal, semolina and flakes derived from maize

- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination, should be excluded from further consideration.
- The EU proposes to recalculate the effect of hypothetical MLs on aflatoxins through the

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<sup>3</sup> Code of Practice for the prevention and reduction of mycotoxin contamination in cereals (CXC 51-2003).

consumption of flour, meal, semolina and flakes derived from maize (table 8) after the exclusion of the outliers.

- The EU does not agree to establishing a maximum level resulting in a very low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins.

- The EU consequently proposes to re-discuss the maximum level proposed for flour, meal, semolina and flakes derived from maize on this basis taking into account an acceptable rejection rate (< 5 %) and the reduction of the human exposure to aflatoxins.

#### Maximum level proposed for husked rice

- Occurrence data on contaminants in food are provided to GEMS/Food database by EFSA on behalf of all EU Member States. The origin of the few data reported in Table 9 for individual EU Member States (Austria, Finland, France, Lithuania, Romania, Slovakia, Spain, Sweden) is therefore unclear. The EU proposes not to use these data for the discussion on the establishment of maximum levels.

- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination, should be excluded from further consideration.

- The EU furthermore proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of husked rice (table 12) after the exclusion of the outliers and the few data in the table as reported to be originating from individual EU Member States.

- The EU does not agree to establishing a maximum level resulting in a low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins.

- The EU consequently proposes to re-discuss the maximum level proposed for husked rice on this basis taking into account an acceptable rejection rate (up to 5 %) and the reduction of the human exposure to aflatoxins.

#### Maximum level proposed for polished rice

- Occurrence data on contaminants in food are provided to GEMS/Food database by EFSA on behalf of all EU Member States. The origin of the few data reported in Table 13 for individual EU Member States (Bulgaria, Czech Republic, Finland, Hungary Ireland, Luxembourg, Romania, Slovakia, Spain) is therefore unclear. The EU proposes not to use these data for the discussion on the establishment of maximum levels.

- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination, should be excluded from further consideration.

- The EU furthermore proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of polished rice (table 16) after the exclusion of the outliers and the few data in the table as reported to be originating from individual EU Member States.

- The EU does not agree to establishing a maximum level resulting in a very low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins.

- The EU consequently proposes to re-discuss the maximum level proposed for polished rice on this basis taking into account an acceptable rejection rate (up to 5 %) and the reduction of the human exposure to aflatoxins.

### Maximum level proposed for sorghum grain destined for further processing

- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination, should be excluded from further consideration.
- The EU furthermore proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of sorghum grain for further processing (table 20) after the exclusion of the outliers.
- The EU does not agree to establishing a maximum level resulting in a low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins.
- The EU consequently proposes to re-discuss the maximum level proposed for sorghum grain on this basis taking into account an acceptable rejection rate (up to 5 %) and the reduction of the human exposure to aflatoxins.

### Maximum level proposed for cereal based foods for infants and young children

- Occurrence data on contaminants in food are provided to GEMS/Food database by EFSA on behalf of all EU Member States. The origin of the few data reported in Table 21 for individual EU Member States (Bulgaria, Czech Republic, Finland, France, Germany, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovenia, Spain) is therefore unclear. The EU proposes not to use these data for the discussion on the establishment of maximum levels.
- The EU is of the opinion that it would be appropriate to present the frequency distribution curve of the occurrence data as outlined above in order to be able to identify possible clear outliers. These outliers, clearly not reflecting the application of good practices to prevent aflatoxin contamination, should be excluded from further consideration.
- The EU furthermore proposes to recalculate the effect of hypothetical MLs on aflatoxins through the consumption of cereal-based foods for infants and young children (table 24) after the exclusion of the outliers and the data in the table as reported to be originating from individual EU Member States.
- The EU does not agree to establishing a maximum level resulting in a very low rejection rate while setting a lower maximum level with still an acceptable rejection rate (< 5%) would result in a significant reduction of the human exposure to aflatoxins.
- The EU consequently proposes to re-discuss the maximum level proposed for cereal-based foods for infants and young children on this basis taking into account an acceptable rejection rate (up to 5 %) and the reduction of the human exposure to aflatoxins.

## APPENDIX I - OTHER MATTERS

- a) The EU is of the opinion that sampling plans and performance criteria for the analysis of total aflatoxins for the food categories for which an ML is proposed to be established should be developed.
- b) The EU does not agree to establishing performance criteria for AFs that consider 70% of total aflatoxins would be AFB1 and the remaining 30% to be distributed equally between AFB2, AFG1 and AFG2. The EU proposes to establish performance criteria for aflatoxins total.
- c) The EU provides has extensive legislation on the sampling and analysis of aflatoxins in food. All information on analytical methods and sampling plans for the analysis of aflatoxins in cereals and cereal-based products is provided in Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R0401-0140701&qid=1592166175696&from=EN>).

### Relevant provisions in Commission Regulation (EC) No 401/2006:

#### ANNEX I - Methods of sampling

- A) General provisions
- B) Methods of sampling for cereals and cereal products
- J) Methods of sampling for baby foods and processed cereal based foods for infants and young children
- L) Method of sampling for very large lots or lots stored or transported in a way whereby sampling throughout the lot is not feasible

#### ANNEX II – Criteria for sample preparation and for methods of analysis used for the official control of the levels of mycotoxins in foodstuffs

- 1) Introduction → 1.1. Precautions
- 2) Treatment of the sample as received by the laboratory
- 3) Replicate samples
- 4) Methods of analysis to be used by the laboratory and laboratory control requirements
  - 4.1. Definitions
  - 4.2. General requirements
  - 4.3. Specific requirements
    - 4.3.1.1. a) Performance criteria for aflatoxins
      - 4.3.1.1.1. i) Notes to the performance criteria for the mycotoxins
      - 4.3.1.1.2. 'Fitness-for-purpose' approach
    - 4.3.2. Specific requirements for semi-quantitative screening methods
  - 4.4. Estimation of measurement uncertainty, recovery calculation and reporting of results